DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

February 24, 2015

Parkell, Inc.
Mr. David Mott
VP, Regulatory Affairs
300 Executive Drive
Edgewood, New York 11717

Re: K142848
Trade/Device Name: Eazy Primer™
Regulation Number: 21 CFR 872.3200
Regulation Name: Resin Tooth Bonding Agent
Regulatory Class: Class II
Product Code: KLE
Dated: January 20, 2015
Received: January 22, 2015

Dear Mr. Mott:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Erin I. Keith, M.S.
Director
Division of Anesthesiology,
General Hospital, Respiratory, Infection
Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K142848

Device Name
EAZY PRIMER™

Indications for Use *(Describe)*
EAZY PRIMER™ is indicated for use in enhancing bonding between dental ceramics (such as porcelain, lithium disilicate, zirconia or hybrid ceramics) and methacrylate resin-based materials. In addition, EAZY PRIMER™ is indicated for use in enhancing bonding between fractured dental ceramics and methacrylate resin-based materials during intra-oral repair of damaged restorations.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

1. **Submitter:**

Parkell, Inc.
300 Executive Drive
Edgewood, NY 11717

2. **Contact:**

David Mott, Esq.
VP, Regulatory Affairs
Tel: (631) 249-1134, ext. 145
Fax: (631) 249-1242

3. **Submission Date:** September 29, 2014

4. **Device Identification:**

Trade Name:	EAZY PRIMER™
Common Name:	Dental Primer
Classification Name:	Resin Tooth Bonding Agent (21 CFR Section 872.3200)
Product Code:	KLE
Classification:	Class II

5. **Predicate and Reference Devices:**

Predicate Device: Etch Free™ (510k no. 896719, filed as Primer-P Adhesive Agent)
Reference Device: Z-PRIME Plus™ Primer (510K no. 091705, filed as Primer Plus)

6. **Description of Applicant Device:**

EAZY PRIMER™ is a two-part, self-cured dental primer which is used for enhancing the bond between dental ceramics (such as porcelain, lithium disilicate, zirconia, or hybrid ceramics) and methacrylate resin-based materials. The device is intended to be used to prepare surface treatments of restorations and repairs.

The device comprises both a silane-coupling agent and a phosphate-coupling agent which generate significant bond strengths between dental ceramic surfaces and methacrylate resin-based materials. As a consequence, like many FDA-cleared and legally-marketed dental primers, EAZY PRIMER™ enables users to enhance bonding between these surfaces without first using an etchant.

7. **Indications for Use:**

EAZY PRIMER™ is indicated for use in enhancing bonding between dental ceramics (such as porcelain, lithium disilicate, zirconia or hybrid ceramics) and methacrylate resin-based materials. In addition, EAZY PRIMER™ is indicated for use in enhancing bonding between fractured dental ceramics and methacrylate resin-based materials during intra-oral repair of damaged restorations.

300 Executive Drive, Box 9004
Edgewood, New York 11717 USA
Toll-Free: 800.243.7446
Phone: 631.249.1134
FAX: 631.249.1242
www.parkell.com

8. **Technological Characteristics:**
EAZY PRIMER™ is a two-part, self-cured dental primer. It is packaged in two 5-milliliter bottles ("bottle A" and "bottle B"), which will be mixed in a 1:1 ratio just prior to use.

All components of EAZY PRIMER™ are found in legally marketed predicate devices. The EAZY PRIMER™ is based upon industry standard monomer chemistry and has similar technological characteristics as other legally marketed dental primers.

9. **Biocompatibility:**

An evaluation of biocompatibility was conducted to determine the safety of EAZY PRIMER™ in accordance with ISO 10993-1: 2009, ISO 10993-5: 2009, ISO 10993-12: 2009, and the guidance document, "Blue Book Memo, G95-1, Use of International Standard ISO-10993, and Biological Evaluation of Medical Devices: Part 1: Evaluation and Testing". The biocompatibility evaluation included cytotoxicity testing in accordance with ISO 10993-5:2009. The conclusion of the evaluation is that EAZY PRIMER™ can be considered biocompatible.

10. **Substantial Equivalence:**

Information provided in this 510(k) submission demonstrates that EAZY PRIMER™ is substantially equivalent to the predicate device, Parkell Inc.'s existing Etch Free™ Primer (K896719) in terms of enhancing bonding to non-zirconia ceramics, as well as to the reference device (K091705) in terms of enhancing bonding to zirconia. The Shear Bond Strength tests were performed in accordance with ISO/TS 11405.

The minor differences between the device and the predicate device do not raise any new questions of safety or effectiveness. Thus, this submission demonstrates the safety and effectiveness of EAZY PRIMER™. A brief comparison of EAZY PRIMER™ to the predicate and reference devices is provided below:

Property (pass/fail criteria, if applicable)	**EAZY PRIMER™ (Parkell, Inc.)**	**Predicate Device** (Etch Free™) (Parkell, Inc.)	**Reference Device** (Z-PRIME Plus®) (Bisco, Inc.)
Intended use	Surface treatment to enhance restorations and repairs.	Surface treatment to enhance restorations and repairs.	Surface treatment to enhance restorations and repairs.
Self-Cure	Yes	Yes	Yes
Shelf Life	3 years	3 years	2 years
Shear Bond Strength to Porcelain (>10MPa)	>10MPa	>10MPa	Not available
Shear Bond Strength to lithium disilicate (>10MPa)	>10MPa	>10MPa	Not available
Shear Bond Strength to zirconia (>10MPa)	>10MPa	Not available	>10MPa